

Remarks

Reconsideration of this Application is respectfully requested.

I. Status Of The Claims, Support For The Amendment, And Reasons For Entry

Applicants propose to amend claims 1, 2, 7, 9 and 10. Support for the proposed amendments is found in the present specification. Applicants also propose to cancel claims 11, 48 and 49 without prejudice to or disclaimer of the subject matter therein.

No new matter will be added by the proposed amendments. Entry of the proposed amendments will not raise new issues that would require further consideration and/or search. Entry of the proposed amendment will also place the application in better form for allowance or appeal, should an appeal be necessary.

Applicants respectfully request that the proposed amendment be considered and entered.

II. The Rejection Of Claim 11 Under 35 U.S.C. § 112, First Paragraph, For Lack Of Enablement, Should Be Withdrawn

At page 3 of the Office Action, the Examiner rejected claim 11 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Applicants respectfully traverse this rejection.

The Examiner stated:

[C]laim 9 [from which claim 11 depends] is drawn to gene regulation systems comprising one or more receptor complexes, that is, receptor protein complexes (claim 9 a) i) A, B C). Therefore, claim 11, which is drawn to a virus comprising the multiple gene regulation system of claim 9 recite [sic] a virus comprising not only nucleic acids, but receptor complexes (proteins) as well.

Office Action at page 5 (emphasis in original).

It is believed that the cancellation of claim 11 would obviate the ground for this rejection. Applicants respectfully request that the proposed amendment be entered, and that this rejection be reconsidered and withdrawn.

III. The Rejection Of Claims 1-4, 7-12, 15, 48 And 49 Under 35 U.S.C. § 112, First Paragraph, For Lack Of Written Description, Should Be Withdrawn

At page 5 of the Office Action, the Examiner rejected claims 1-4, 7-12, 15, 48 and 49 under 35 U.S.C. § 112, first paragraph, for lack of written description. Applicants respectfully traverse this rejection.

At page 5 of the Office Action, the Examiner stated:

The claims are directed to a genus of an essentially unlimited scope of multiple gene regulation systems comprising two or more individually operable gene regulation systems, wherein each individual system operates independently of any other ("is orthogonal"). However, the only systems described are ones comprising two independent systems (Examples 1 and 2), a Leidopteran/Dipteran and a Lepidopteran/Homopteran ecdysone receptor system. Applicant has not identified any particular structure of the ligand binding domains of the components of the gene regulation system that will provide the required specificity and uniqueness of binding between the ligand and the receptor for use in the claimed multiple orthogonal systems, but has identified the claimed systems solely by function.

Pending claims 48 and 49 depend from independent claims 1 and 9, respectively, and recite that the multiple inducible gene regulation system consists of two orthogonal gene regulation systems. Applicants propose to cancel claims 48 and 49 and to amend each of independent claims 1 and 9 to recite a multiple inducible gene regulation system consisting of two orthogonal gene regulation systems.

With respect to claims 48 and 49, the Examiner stated:

Claims 48 and 49 are directed to multiple inducible gene regulation systems wherein said systems consist of two individually operable gene regulation systems. The claims encompass systems comprising the ligand binding domains (LBD) of any Group H nuclear receptor and the LBD of any nuclear receptor capable of forming a dimer [sic]. with said Group H nuclear receptor LBD.

However, claims 48 and 49 encompass multiple systems, comprising a plurality of individually operated gene regulation systems which have not been further described. The skilled artisan would not recognize that applicants were in possession of a genus of multiple expression systems. Applicants have not identified any particular chemical structure that will provide the required specificity and uniqueness of binding between the ligand and the receptor for use in the claimed multiple orthogonal systems, but have identified the claimed systems solely by function.

Pages 40-43 of the specification [paragraphs 0204-0240], disclose complex, art-recognized methods of searching for specific ligands and screening for novel cognate LBDs. The structures of ligands presented on page 40, as potential chemotypes ideal for use as ligands, comprise a natural ecdysteroid and known diacylhydrazine. These compounds appear to be cross-interactive across insect species, which is contrary to that required by the claimed invention, that the multiple systems be orthogonal. Applicants teach that "an orthogonal ligand/receptor set does not exist within these two structural families". This is certainly not evidence of possession but indicates that to achieve the goal of a multiple, orthogonal gene regulation system, as broadly claimed, further experimentation is required (page 40, lines 8-15, paragraph 0205).

Thus, applicants have not disclosed any additional molecules as ligands nor have they identified any particular cognate LBDs. The methods outlined act as an invitation to design and discover which ligands-receptor pairs may work as the multiple gene regulatory systems of the instant invention.

Applicants are not in possession of the claimed genus of "multiple inducible gene modulation system" and thus, the current claims do not comply with the requirement for written description under 35 USC 112, first paragraph.

Therefore, the Lepidopteran/Dipteran and Lepidopteran/Homopteran receptor schemes (of the Group H family of receptors) but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph.

Office Action at pages 6-8.

Applicants respectfully disagree. The test for written description is whether the description provides that the inventors were in possession of the claimed invention. *See* M.P.E.P. § 2163.02 (citations omitted). Here, that test is met, because the present application clearly establishes that the inventors were in possession of the presently claimed invention.

Moreover, it is not necessary for an applicant to have reduced a claimed invention to practice, in order to have described the invention. *See Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006), where the Federal Circuit stated:

[W]e hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Furthermore, it is not necessary for an application to disclose every permutation of a claimed invention in order to have described the invention. *See Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005). Instead, the level of disclosure required turns on

the predictability of the technology. *See id.* at 1360 ("The predictability or unpredictability of the science is relevant to deciding how much experimental support is required to adequately describe the scope of an invention.").

Indeed, less disclosure is required for more predictable technologies. "The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge." *Id.* at 1358. Moreover, the level of description need to comply with the written description requirement

varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

Id. at 1357.

Applicants have exemplified two different orthogonal two-gene switch systems. *See* the present application at pages 56-60. In addition, Applicants have disclosed at pages 40-44 of the specification detailed approaches for identifying orthogonal, ligand/receptor pairs that can be used to construct other orthogonal two-gene switch systems.

The Examiner has not questioned whether, given the disclosure in the present specification, one of ordinary skill in the art would have been able to practice the claimed invention without undue experimentation. The disclosure of the present specification is not merely an invitation to experiment. Instead, the present specification discloses the claimed invention.

Applicants respectfully request that this rejection be reconsidered and withdrawn.

Conclusion

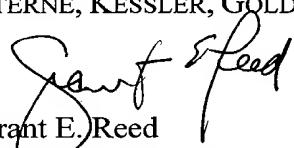
All of the stated grounds of objection and rejection have been properly traversed or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw the presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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